

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listing, of claims in the application:

## Listing of Claims:

Claim 1. (Twice amended) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

providing a solid pharmaceutical composition for oral administration to the subject, the composition emprising consisting essentially of: (a) a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor; and an amount of (b) at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid so as to achieve an initial scrum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after administration of the composition; in an amount of about 0.1 mEq to about 2.5 mEq per mg proton pump inhibitor; and (c) one or more optional pharmaceutically acceptable excipients; and

orally administering the pharmaceutical composition to the subject,

wherein upon oral administration of the pharmaceutical composition to the subject, an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml is obtained at any time within about 30 minutes after administration of the composition.

Claim 2. (Previously amended) The method of claim 1, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor



greater than about  $0.15 \mu g/ml$  at any time within about 30 minutes after administration of the composition.

Claim 3. (Cancelled)

Claim 4. (Cancelled)

Claim 5. (Cancelled)

Claim 6. (Cancelled)

Claim 7. (Previously cancelled)

Claim 8. (Previously amended) The method of claim 1, wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet, granules, pellets, and a liquid created by mixing any of the foregoing with an aqueous medium.

Claim 9. (Cancelled)

Claim 10. (Previously amended) The method of claim 1, wherein the amount of the proton pump inhibitor absorbed into the serum is therapeutically effective in treating the gastric acid related disorder selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.



Claim N. (Previously amended) The method of claim 1, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 12. (Previously amended) The method of claim 1, wherein the amount of the proton pump inhibitor is about 2 mg to about 300 mg.

Claim 13. (Previously amended) The method of claim 1, wherein the amount of the proton pump inhibitor is about 10 mg to about 120 mg.

Claim 14. (Previously amended) The method of claim 1, wherein the amount of the proton pump inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 15. (Previously cancelled)

Claim 16. (Previously cancelled).

Claim 17. (Cancelled)

Claim 18. (Original) The method of claim 1, wherein the amount of the buffering agent is about 10 mEq to about 70 mEq.



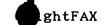
Claim 19. (Original) The method of claim 1, wherein the amount of the buffering agent is at least 10 mEq.

Claim 20. (Previously amended) The method of claim 1, wherein the amount of the buffering agent is about 15 mEq to about 55 mEq.

Claim 21. (Original) The method of claim 1, wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

Claim 32. (Original) The method of claim 1, wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

Claim 23. (Previously amended) The method of claim 1, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, potassium polyphosphate, sodium pyrophosphate, sodium dihydrogen phosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium



carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate,

trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

Claim 24. (Previously cancelled)

Claim 25. (Original) The method of claim 1, wherein the buffering agent comprises sodium bicarbonate.

Claim 26. (Previously amended) The method of claim 25, wherein the sodium bicarbonate is in an amount from about 250 mg to about 4000 mg.

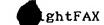
Claim 27. (Previously amended) The method of claim 25, wherein the sodium bicarbonate is in an amount from about 1000 mg to about 2000 mg.

Claim 28. (Previously amended) The method of claim 25, wherein the sodium bicarbonate is in an amount of at least about 400 mg.

Claim 29. (Original) The method of claim 1, wherein the buffering agent comprises calcium carbonate.

Claim 30. (Original) The method of claim 29, wherein the calcium carbonate is in an amount from about 250 mg to about 4000 mg.

Claim 3.?\ (Previously amended) The method of claim 29, wherein the calcium carbonate is in an amount from about 1000 mg to about 2000 mg.



Claim 32. (Previously amended) The method of claim 29, wherein the calcium carbonate is in an amount of at least about 400 mg.

Claim 33. (Previously cancelled)

Claim 34. <sup>23</sup> (Twice amended) The method of claim 1, wherein the eomposition further eomprises at least one of an excipient is selected from the group consisting of, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 35. (Twice amended) The method of claim 1, wherein the eomposition further eomprises excipient is one or more flavoring agents eomprising selected from the group consisting of aspartame, thaumatin, sucrose, dextrose, or a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.

Claim 36. (Original) The method of claim 1, wherein the composition is administered once or twice a day.

Claim 37.

(Previously canceled).

Claim 38

(Previously canceled).

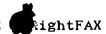
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- Claim 39. (Previously canceled).
- Claim 40. (Previously canceled).
- Claim 41. (Previously canceled).
- Claim 42. (Previously canceled).
- Claim 43. (Previously canceled).
- Claim 44. (Previously canceled).
- Claim 45. (Previously canceled).
- Claim 46. (Previously canceled).
- Claim 47. (Previously canceled)
- Claim 48. (Previously canceled).
- Claim 49. (Previously canceled).
- Claim 50. (Previously canceled).
- Claim 51. (Previously canceled).
- Claim 52. (Previously canceled)
- Claim 53. (Previously canceled).
- Claim 54. (Previously canceled).



- Claim 55. (Previously canceled).
- Claim 56. (Previously canceled).
- Claim 57. (Previously canceled),
- Claim 58. (Previously canceled).
- Claim 59. (Previously canceled).
- Claim 60. (Previously canceled).
- Claim 61. (Previously canceled).
- Claim 62. (Previously canceled).
- Claim 63. (Previously canceled).
- Claim 64. (Previously canceled).
- Claim 65. (Previously canceled).
- Claim 66. (Previously canceled).
- Claim 67. (Previously canceled)
- Claim 68. (Previously canceled).
- Claim 69. (Previously canceled).
- Claim 70. (Previously canceled).



Claim 71. (Previously canceled).

Claim 72. (Previously canceled).

Claim 73. (Previously canceled).

Claim 74. (Previously canceled)

Claim 75. (Twice amended) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

pharmaceutical composition in an oral dosage form for immediate release into an absorption pool having a highly acidic pH, the composition comprising consisting essentially of: (a) a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor; and an amount of (b) at least one buffering agent sufficient to increase the pH of the absorption pool of the subject to a pH that prevents acid degradation of at least some of the proton pump inhibitor so as to achieve in an amount of about 0.1 mEq to about 2.5 mEq per mg proton pump inhibitor; and (c) one or more optional pharmaceutically acceptable excipients wherein an initial serum concentration of the proton pump inhibitor greater than about 0.1 μg/ml is obtained at any time within about 30 minutes after administration of the composition, and wherein the administering step does not require further administration of the buffering agent(s) beyond that administered in the single dose.

Claim 76.<sup>27</sup> (Previously amended) The method of claim 75, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump



inhibitor greater than about  $0.15 \,\mu g/ml$  at any time within about 30 minutes after administration of the composition.

Claim //.	(Cancelled)
Claim 78.	(Cancelled)
Claim 79.	(Cancelled)
Claim 80.	(Cancelled)
Claim & L.	(Original) The method of claim 75, wherein the subject is fasting.
Claim 82.	(Cancelled)

Claim 85. (Previously amended) The method of claim 35, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 86. (Previously amended) The method of claim 85, wherein the amount of the proton pump inhibitor is about 2 mg to about 300 mg.

Claim 87. (Previously amended) The method of claim %, wherein the amount of the proton pump inhibitor is about 10 mg to about 120 mg.

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Claim 83.

Claim 84.

(Cancelled)

(Previously Cancelled)

Claim 88. (Previously amended) The method of claim 75, wherein the amount of the proton pump inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 89. (Previously cancelled)

Claim 90. (Previously cancelled)

Claim 91. (Cancelled)

Claim 92. (Original) The method of claim 75, wherein the amount of the buffering agent is about 10 mEq to about 70 mEq.

Claim 93. (Original) The method of claim 75, wherein the amount of the buffering agent is at least 10 mEq.

Claim 94. (Previously amended) The method of claim 75, wherein the amount of the buffering agent is about 15 mEq to about 55 mEq.

Claim 95. (Original) The method of claim 95, wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

Claim %. (Original) The method of claim %, wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.



(Previously amended) The method of claim 35, wherein the buffering Claim 37. agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

Claim 98.

(Previously cancelled)

Claim 99. (Original) The method of claim 75, wherein the buffering agent comprises sodium bicarbonate.

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Claim 190. (Original) The method of claim 99, wherein the sodium bicarbonate is in an amount from about 250 mg to about 4000 mg.

Claim 101. (Previously amended) The method of claim 39, wherein the sodium bicarbonate is in an amount from about 1000 mg to about 2000 mg.

Claim 102. (Previously amended) The method of claim 99, wherein the sodium bicarbonate is in an amount of at least about 400 mg.

Claim 193. (Original) The method of claim 75, wherein the buffering agent comprises calcium carbonate.

Claim 194. (Original) The method of claim 193, wherein the calcium carbonate is in an amount from about 250 mg to about 4000 mg.

Claim 195. (Previously amended) The method of claim 193, wherein the calcium carbonate is in an amount from about 1000 mg to about 2000 mg.

Claim 196. (Previously amended) The method of claim 193, wherein the calcium carbonate is in an amount of at least about 400 mg.

Claim 107. (Previously cancelled)

Claim 198. (Twice amended) The method of claim 75, wherein the composition further comprises at least one of an excipient is selected from the group consisting of, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a



moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 109. (Original) The method of claim 75, wherein the subject is an adult human.

Claim H0. (Previously amended) The method of claim 75, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.

Claim 131. (Twice amended) The method of claim 25, wherein the emposition further comprises excipient is one or more flavoring agents comprising selected from the group consisting of aspartame, thaumatin, sucrose, dextrose, of a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.

Claim 112. (Original) The method of claim 35, wherein the composition is administered once or twice a day.

Claim 113. (Withdrawn) A method of making a pharmaceutical composition for oral administration to a subject, comprising:



admixing a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor, and an amount of at least one buffering agent sufficient to increase the pH of an absorption pool of the subject to a pH that prevents acid degradation of at least some of the proton pump inhibitor so as to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after administration of the composition

Claim 114. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml at any time within about 30 minutes after administration of the composition.

Claim 115. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15  $\mu$ g/ml from about 10 minutes to about 30 minutes after administration of the composition.

Claim 116. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 20 minutes after administration of the composition.

Claim 117. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor



greater than about 0.1 µg/ml at any time within about 15 minutes after administration of the composition.

Claim 118. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml at any time within about 15 minutes after administration of the composition.

Claim 119. (Previously cancelled)

Claim 120. (Withdrawn) The method of claim 113, wherein the pharmaceutical composition is in a form selected from the group consisting of a tablet, capsule, powder, suspension tablet, effervescent tablet or capsule, chewable tablet, granules, pellets, and a liquid created by mixing any of the foregoing with an aqueous medium.

Claim 121. (Withdrawn) The method of claim 113, wherein at least some of the proton pump inhibitor is coated.

Claim 122. (Withdrawn) The method of claim 113, wherein the proton pump inhibitor is acid sensitive.

Claim 123. (Withdrawn) The method of claim 113, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.



Claim 124. (Withdrawn) The method of claim 113, wherein the amount of the proton pump inhibitor is about 2 mg to about 300 mg.

Claim 125. (Withdrawn) The method of claim 113, wherein the amount of the proton pump inhibitor is about 10 mg to about 120 mg.

Claim 126. (Withdrawn) The method of claim 113, wherein the amount of the proton pump inhibitor is about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 127.

(Previously cancelled)

Claim 128

(Previously cancelled)

Claim 129. (Withdrawn) The method of claim 113, wherein the amount of the buffering agent is about 0.1 mEq to about 2.5 mEq per mg of proton pump inhibitor.

Claim 130. (Withdrawn) The method of claim 113, wherein the amount of the buffering agent is about 10 mEq to about 70 mEq.

Claim 131. (Withdrawn) The method of claim 113, wherein the amount of the buffering agent is at least 10 mEq.

Claim 132. (Withdrawn) The method of claim 113, wherein the amount of the buffering agent is about 15 mEq to about 55 mEq.

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Claim 133. (Withdrawn) The method of claim 113, wherein the buffering agent comprises a combination of calcium carbonate and sodium bicarbonate.

Claim 134. (Withdrawn) The method of claim 113, wherein the buffering agent comprises a bicarbonate salt of a Group IA metal.

Claim 135. (Withdrawn) The method of claim 113, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

- Claim 136. (Previously cancelled)
- Claim 137. (Withdrawn) The method of claim 113, wherein the buffering agent comprises sodium bicarbonate.
- Claim 138. (Withdrawn) The method of claim 137, wherein the sodium bicarbonatc is in an amount from about 250 mg to about 4000 mg.
- Claim 139. (Withdrawn) The method of claim 137, wherein the sodium bicarbonate is in an amount from about 1000 mg to about 2000 mg.
- Claim 140. (Withdrawn) The method of claim 137, wherein the sodium bicarbonate is in an amount of at least about 400 mg.
- Claim 141. (Withdrawn) The method of claim 113, wherein the buffering agent comprises calcium carbonate.
- Claim 142. (Withdrawn) The method of claim 141, wherein the calcium carbonate is in an amount from about 250 mg to about 4000 mg.
- Claim 143. (Withdrawn) The method of claim 141, wherein the calcium carbonate is in an amount from about 1000 mg to about 2000 mg.
- Claim 144. (Withdrawn) The method of claim 141, wherein the calcium carbonate is in an amount of at least about 400 mg.
  - Claim 145. (Previously cancelled)



Claim 146. (Withdrawn) The method of claim 113, wherein the composition further comprises at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 147. (Withdrawn) The method of claim 113, wherein the subject has a gastric acid related disorder.

Claim 148. (Withdrawn) The method of claim 147, wherein the disorder is selected from the group consisting of duodenal ulcer disease, gastric ulcer disease, gastroesophageal reflux disease, erosive esophagitis, poorly responsive symptomatic gastroesophageal reflux disease, pathological gastrointestinal hypersecretory disease, Zollinger Ellison Syndrome, heartburn, esophageal disorder, and acid dyspepsia.

Claim 149. (Withdrawn) The method of claim 113, wherein the composition further comprises one or more flavoring agents comprising aspartame, thaumatin, sucrose, dextrose, or a chocolate, a cocoa, a cola, a peppermint, a spearmint, a watermelon, an apple, a caramel, a meat, a root beer, a maple, a cherry, a coffee, a mint, a licorice, a nut, a butter, a butterscotch, a butter pecan, or a peanut butter flavoring, and combinations of any of the foregoing.

Claim 150. (Withdrawn) The method of claim 113, wherein the composition is administered once or twice a day.

Claim 151. (Withdrawn) The method of claim 1, wherein the amount of the proton pump inhibitor absorbed into the serum is therapeutically effective in treating the gastric acid related disorder selected from the group consisting of a non-erosive reflux disorder, and an NSAID induced ulcer.

Claim 152. (Withdrawn) The method of claim 75, wherein the disorder is selected from the group consisting of a non-erosive reflux disorder, and an NSAID induced ulcer.

Claim 153. (Withdrawn) The method of claim 147, wherein the disorder is selected from the group consisting of a non-erosive reflux disorder, and an NSAID induced ulcer.

Claim 154. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: (a) at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor in an amount of about 2 mg to about 300 mg; and (b) at least one buffering agent in an amount of about 0.1 mEq to about 2.5 mEq per mg of proton pump inhibitor, provided that the amount of the buffering agent is sufficient to elevate pH of stomach secretions upon oral administration to the subject to prevent acid degradation of at least some of the proton pump inhibitor in the stomach secretions to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after administration of the composition;

wherein the composition is free of sucralfate, and

wherein if the composition is other than a dosage form selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, effervescent tablet, and troche, then

the buffering agent is in an amount that is more than about 40 times the amount of proton pump inhibitor on a weight to weight basis in the composition.

Claim 155. (Withdrawn) The composition of claim 154, wherein the composition is a dosage form selected from the group consisting of tablet, capsule, powder, pellets, and granules.

Claim 156. (Withdrawn) The composition of claim 154, wherein at least some of the proton pump inhibitor is coated prior to administration.

Claim 157. (Withdrawn) The composition of claim 154, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 158. (Withdrawn) The composition of claim 157, wherein the proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 159. (Withdrawn) The composition of claim 157, wherein the omeprazole is present in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.



Claim 160. (Withdrawn) The composition of claim 157, wherein the proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 161. (Withdrawn) The composition of claim 160, wherein the lansoprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 162. (Withdrawn) The composition of claim 154, further comprising at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 163. (Withdrawn) The composition of claim 154, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum



hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

- (Withdrawn) The composition of claim 154, wherein the amount of the Claim 164. buffering agent present in the composition is about 0.5 mEq to about 150 mEq.
- Claim 165. (Withdrawn) The composition of claim 154, wherein the amount of the buffering agent present in the composition is about 5 mEq to about 30 mEq.
- (Withdrawn) The composition of claim 154, wherein the amount of the Claim 166. buffering agent present in the composition is about 15 mEq to about 55 mEq.
- (Withdrawn) The composition of claim 154, wherein the buffering agent Claim 167. is sodium bicarbonate.
- Claim 168. (Withdrawn) The composition of claim 167, wherein the amount of the sodium bicarbonate present in the composition is about 2 mEq to about 70 mEq. 13105589 02936354



- Claim 169. (Withdrawn) The composition of claim 167, wherein the amount of the sodium bicarbonate present in the composition is about 10 mEq to about 55 mEq.
- Claim 170. (Withdrawn) The composition of claim 167, wherein the amount of the sodium bicarbonate present in the composition is about 12.5 mEq to about 30 mEq.
- Claim 171. (Withdrawn) The composition of claim 167, wherein the amount of the sodium bicarbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.
- Claim 172. (Withdrawn) The composition of claim 154, wherein the buffering agent is calcium carbonate.
- Claim 173. (Withdrawn) The composition of claim 172, wherein the amount of the calcium carbonate present in the composition is about 2 mEq to about 70 mEq.
- Claim 174. (Withdrawn) The composition of claim 172, wherein the amount of the calcium carbonate present in the composition is about 10 mEq to about 55 mEq.
- Claim 175. (Withdrawn) The composition of claim 172, wherein the amount of the calcium carbonate present in the composition is about 12.5 mEq to about 30 mEq.
- Claim 176. (Withdrawn) The composition of claim 172, wherein the amount of the calcium carbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.



- Claim 177. (Withdrawn) The composition of claim 154, wherein the buffering agent is a mixture of sodium bicarbonate and calcium carbonate.
- Claim 178. (Withdrawn) The composition of claim 177, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 2 mEq to about 70 mEq.
- Claim 179. (Withdrawn) The composition of claim 177, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 10 mEq to about 55 mEq.
- Claim 180. (Withdrawn) The composition of claim 177, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 12.5 mEq to about 30 mEq.
- Claim 181. (Withdrawn) The composition of claim 177, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.
- Claim 182. (Withdrawn) The composition of claim 154, wherein all or part of the proton pump inhibitor is micronized.
- Claim 183. (Withdrawn) The composition of claim 154, wherein all or part of the buffering agent is micronized.
- Claim 184. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1 hour after administration of the composition.



Claim 185. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 186. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 187. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 30 minutes after administration of the composition.

Claim 188. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 10 minutes to about 30 minutes after administration of the composition.

Claim 189. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml at any time within about 20 minutes after administration of the composition.



Claim 190. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 15 minutes after administration of the composition.

Claim 191. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 15 minutes after administration of the composition.

Claim 192. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: (a) at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor in an amount of about 2 mg to about 300 mg; and (b) at least one buffering agent in a total amount greater than about 10 mEq, provided that the amount of the buffering agent is sufficient to elevate pH of stomach secretions upon oral administration to the subject to prevent acid degradation of at least some of the proton pump inhibitor in the stomach secretions to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after ingestion of the composition; and

wherein if the composition is other than a dosage form selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, effervescent tablet, and troche, then the buffering agent is in an amount that is more than about 40 times the amount of proton pump inhibitor on a weight to weight basis in the composition.





Claim 193. (Withdrawn) The composition of claim 192, wherein the composition is a dosage form selected from the group consisting of tablet, capsule, powder, pellets, and granules.

Claim 194. (Withdrawn) The composition of claim 192, wherein the composition is a dosage form selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, effervescent tablet, and troche.

Claim 195. (Withdrawn) The composition of claim 192, wherein the proton pump inhibitor is enteric coated prior to administration.

Claim 196. (Withdrawn) The composition of claim 192, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 197. (Withdrawn) The composition of claim 196, wherein the proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 198. (Withdrawn) The composition of claim 192, wherein the omeprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.



Claim 199. (Withdrawn) The composition of claim 196, wherein the proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 200. (Withdrawn) The composition of claim 192, the lansoprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 201. (Withdrawn) The composition of claim 192, further comprising at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 202. (Withdrawn) The composition of claim 192, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum



hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium pyrophosphate, sodium pyrophosphate, sodium pyrophosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.

Claim 203. (Withdrawn) The composition of claim 192, wherein the total amount of the buffering agent is greater than about 16 mEq.

Claim 204. (Withdrawn) The composition of claim 192, wherein the total amount of the buffering agent is greater than about 20 mEq.

Claim 205. (Withdrawn) The composition of claim 192, wherein the total amount of the buffering agent present in the composition is about 16 mEq to about 150 mEq.

Claim 206. (Withdrawn) The composition of claim 192, wherein the total amount of the buffering agent present in the composition is about 16 mEq to about 30 mEq.

Claim 207. (Withdrawn) The composition of claim 192, wherein the total amount of the buffering agent present in the composition is about 15 mEq to about 55 mEq.



Claim 208. (Withdrawn) The composition of claim 192, wherein at least one buffering agent is sodium bicarbonate.

Claim 209. (Withdrawn) The composition of claim 208, wherein the amount of the sodium bicarbonate present in the composition is about 2 mEq to about 70 mEq.

Claim 210. (Withdrawn) The composition of claim 208, wherein the amount of the sodium bicarbonate present in the composition is about 10 mEq to about 55 mEq.

Claim 211. (Withdrawn) The composition of claim 208, wherein the amount of the sodium bicarbonate present in the composition is about 12.5 mEq to about 30 mEq.

Claim 212. (Withdrawn) The composition of claim 208, wherein the amount of the sodium bicarbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 213. (Withdrawn) The composition of claim 192, wherein at least one buffering agent is calcium carbonate.

Claim 214. (Withdrawn) The composition of claim 213, wherein the amount of the calcium carbonate present in the composition is about 2 mEq to about 70 mEq.

Claim 215. (Withdrawn) The composition of claim 213, wherein the amount of the calcium carbonate present in the composition is about 10 mEq to about 55 mEq.

Claim 216. (Withdrawn) The composition of claim 213, wherein the amount of the calcium carbonate present in the composition is about 12.5 mEq to about 30 mEq.



- Claim 217. (Withdrawn) The composition of claim 213, wherein the amount of the calcium carbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.
- Claim 218. (Withdrawn) The composition of claim 192, wherein the buffering agent is a mixture of sodium bicarbonate and calcium carbonate.
- Claim 219. (Withdrawn) The composition of claim 218, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 2 mEq to about 70 mEq.
- Claim 220. (Withdrawn) The composition of claim 218, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 10 mEq to about 55 mEq.
- Claim 221. (Withdrawn) The composition of claim 218, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 12.5 mEq to about 30 mEq.
- Claim 222. (Withdrawn) The composition of claim 218, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.
- Claim 223. (Withdrawn) The composition of claim 192, wherein all or part of the proton pump inhibitor is micronized.
- Claim 224. (Withdrawn) The composition of claim 192, wherein all or part of the buffering agent is micronized.



Claim 225. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1 hour after administration of the composition.

Claim 226. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 227. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 228. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 30 minutes after administration of the composition.

Claim 229. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 10 minutes to about 30 minutes after administration of the composition.

Claim 230. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 20 minutes after administration of the composition.

Claim 231. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 15 minutes after administration of the composition.

Claim 232. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 15 minutes after administration of the composition.

Claim 233. (Withdrawn) A pharmaceutical composition in a form of a commercially stable powder for suspension useful in the treatment of acid-caused gastrointestinal disorders, comprising: a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor, at least one buffering agent in an amount of about 0.1 mEq to about 2.5 mEq per mg of the proton pump inhibitor, and at least one thickening agent to reduce settling of the proton pump inhibitor after constitution with an aqueous medium; provided that the amount of the buffering agent is sufficient to elevate pH of stomach secretions upon oral administration to a subject to prevent acid degradation of at least some of the proton pump inhibitor in the stomach secretions to achieve an initial serum



concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after administration of the composition.

Claim 234. (Withdrawn) The composition of claim 233, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 235. (Withdrawn) The composition of claim 234, wherein the proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 236. (Withdrawn) The composition of claim 235, wherein the omeprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 237. (Withdrawn) The composition of claim 234, wherein the proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 238. (Withdrawn) The composition of claim 237, wherein the lansoprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, 13105589 02936354



about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 239. (Withdrawn) The composition of claim 233, further comprising at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

Claim 240. (Withdrawn) The composition of claim 233, wherein the buffering agent is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium pyrophosphate, potassium polyphosphate, sodium pyrophosphate, trisodium phosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium

amino acid, and combinations of any of the foregoing.

Patent Application Serial No. 10/054,350 Amendment dated September 22, 2003 Reply to Office Action of August 6, 2003 Docket No. 02936354

carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate
magnesium phosphate, potassium phosphate, sodium phosphate,
trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an

- Claim 241. (Withdrawn) The composition of claim 233, wherein the amount of the buffering agent present in the composition is about 0.5 mEq to about 150 mEq.
- Claim 242. (Withdrawn) The composition of claim 233, wherein the amount of the buffering agent present in the composition is about 5 mEq to about 30 mEq.
- Claim 243. (Withdrawn) The composition of claim 233, wherein the amount of the buffering agent present in the composition is about 15 mEq to about 55 mEq.
- Claim 244. (Withdrawn) The composition of claim 233, wherein the buffering agent is sodium bicarbonate.
- Claim 245. (Withdrawn) The composition of claim 244, wherein the amount of the sodium bicarbonate present in the composition is about 2 mEq to about 70 mEq.
- Claim 246. (Withdrawn) The composition of claim 244, wherein the amount of the sodium bicarbonate present in the composition is about 10 mEq to about 55 mEq.
- Claim 247. (Withdrawn) The composition of claim 244, wherein the amount of the sodium bicarbonate present in the composition is about 12.5 mEq to about 30 mEq.



Claim 248. (Withdrawn) The composition of claim 244, wherein the amount of the sodium bicarbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 249. (Withdrawn) The composition of claim 233, wherein the buffering agent is calcium carbonate.

Claim 250. (Withdrawn) The composition of claim 249, wherein the amount of the calcium carbonate present in the composition is about 2 mEq to about 70 mEq.

Claim 251. (Withdrawn) The composition of claim 249, wherein the amount of the calcium carbonate present in the composition is about 10 mEq to about 55 mEq.

Claim 252. (Withdrawn) The composition of claim 249, wherein the amount of the calcium carbonate present in the composition is about 12.5 mEq to about 30 mEq.

Claim 253. (Withdrawn) The composition of claim 249, wherein the amount of the calcium carbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 254. (Withdrawn) The composition of claim 233, wherein the buffering agent is a mixture of sodium bicarbonate and calcium carbonate.

Claim 255. (Withdrawn) The composition of claim 254, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 2 mEq to about 70 mEq.

Claim 256. (Withdrawn) The composition of claim 254, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 10 mEq to about 55 mEq.

Claim 257. (Withdrawn) The composition of claim 254, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 12.5 mEq to about 30 mEq.

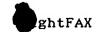
Claim 258. (Withdrawn) The composition of claim 254, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 259. (Withdrawn) The composition of claim 233, wherein all or part of the proton pump inhibitor is micronized.

Claim 260. (Withdrawn) The composition of claim 233, wherein all or part of the buffering agent is micronized.

Claim 261. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1 hour after administration of the composition.

Claim 262. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.



Claim 263. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 264. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 30 minutes after administration of the composition.

Claim 265. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 30 minutes after administration of the composition.

Claim 266. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml at any time within about 20 minutes after administration of the composition.

Claim 267. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 15 minutes after administration of the composition.

Claim 268. (Withdrawn) The composition of claim 233, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 15 minutes after administration of the composition.

Claim 269. (Withdrawn) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

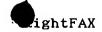
providing a solid pharmaceutical composition for oral administration to the subject, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid; and

orally administering the pharmaceutical composition to the subject;

wherein upon oral administration to the subject, the composition provides a pharmacokinetic profile such that at least about 50% of total area under serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 2 hours after administration of a single dose of the composition to the subject.

Claim 270. (Withdrawn) The method of claim 269, wherein the area under the serum concentration time curve (AUC) for the proton pump inhibitor is at least about 60% of the total area.





Claim 271. (Withdrawn) The method of claim 269, wherein the area under the serum concentration time curve (AUC) for the proton pump inhibitor is at least about 70% of the total area.

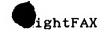
Claim 272. (Withdrawn) The method of claim 269, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.75 hours after administration of a single dose of the composition to the subject.

Claim 273. (Withdrawn) The method of claim 269, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.5 hours after administration of a single dose of the composition to the subject.

Claim 274. (Withdrawn) The method of claim 269, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1 hour after administration of a single dose of the composition to the subject.

Claim 275. (Withdrawn) The method of claim 269, wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 276. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid;



wherein the composition upon oral administration to the subject provides a pharmacokinetic profile such that at least about 50% of total area under serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 2 hours after administration of a single dose of the composition.

Claim 277. (Withdrawn) The composition of claim 276, wherein the area under the serum concentration time curve (AUC) for the proton pump inhibitor is at least about 60% of the total area.

Claim 278. (Withdrawn) The composition of claim 276, wherein the area under the serum concentration time curve (AUC) for the proton pump inhibitor is at least about 70% of the total area.

Claim 279. (Withdrawn) The composition of claim 276, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.75 hours after administration of a single dose of the composition to the subject.

Claim 280. (Withdrawn) The composition of claim 276, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1.5 hours after administration of a single dose of the composition to the subject.

Claim 281. (Withdrawn) The composition of claim 276, wherein the at least about 50% of total area under the serum concentration time curve (AUC) for the proton pump inhibitor occurs within about 1 hour after administration of a single dose of the composition to the subject.

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Claim 282. (Withdrawn) The composition of claim 276 wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 283. (Withdrawn) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

providing a solid pharmaceutical composition for oral administration to the subject, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid; and

orally administering the pharmaceutical composition to the subject;

wherein upon oral administration to the subject, the composition provides a pharmacokinetic profile such that the proton pump inhibitor reaches a maximum serum concentration within about 1 hour after administration of a single dose of the composition.

Claim 284. (Withdrawn) The method of claim 283, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.75 hours.

Claim 285. (Withdrawn) The method of claim 283, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.5 hours.

Claim 286. (Withdrawn) The method of claim 283, wherein the maximum serum concentration is at least about 0.25 µg proton pump inhibitor/ml.



Claim 287. (Withdrawn) The method of claim 283, wherein the maximum serum concentration is at least about 0.5 µg proton pump inhibitor/ml.

Claim 288. (Withdrawn) The method of claim 283, wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 289. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid;

wherein the composition upon oral administration to the subject provides a pharmacokinetic profile such that the proton pump inhibitor reaches a maximum serum concentration within about 1 hour after administration of a single dose of the composition.

Claim 290. (Withdrawn) The composition of claim 289, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.75 hours.

Claim 291. (Withdrawn) The composition of claim 289, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.5 hours.

Claim 292. (Withdrawn) The composition of claim 289, wherein the maximum serum concentration is at least about 0.25 µg proton pump inhibitor/ml.



Claim 293. (Withdrawn) The composition of claim 289, wherein the maximum serum concentration is at least about 0.5 µg proton pump inhibitor/ml.

Claim 294. (Withdrawn) The composition of claim 289, wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 295. (Withdrawn) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

providing a solid pharmaceutical composition for oral administration to the subject, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid; and

orally administering the pharmaceutical composition to the subject;

wherein upon oral administration to the subject, the composition provides a serum concentration of the proton pump inhibitor of at least about 50% of maximum serum concentration within about 45 minutes after administration of a single dose of the composition.

Claim 296. (Withdrawn) The method of claim 295, wherein the 50% of the maximum serum concentration of the proton pump inhibitor is reached within about 30 minutes.

Claim 297. (Withdrawn) The method of claim 295, wherein the 50% of the maximum serum concentration of the proton pump inhibitor is reached within about 15 minutes.



Claim 298. (Withdrawn) The method of claim 295, wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 299. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid;

wherein the composition upon oral administration to the subject provides a serum concentration of the proton pump inhibitor of at least about 50% of maximum serum concentration within about 45 minutes after administration of a single dose of the composition.

Claim 300. (Withdrawn) The composition of claim 299, wherein the 50% of the maximum serum concentration of the proton pump inhibitor is reached within about 30 minutes.

Claim 301. (Withdrawn) The composition of claim 299, wherein the 50% of the maximum serum concentration of the proton pump inhibitor is reached within about 15 minutes.

Claim 302. (Withdrawn) The composition of claim 299, wherein the 50% of the maximum serum concentration is at least about 0.25 µg proton pump inhibitor/ml.

Claim 303. (Withdrawn) The composition of claim 299, wherein the 50% of the maximum serum concentration is at least about 0.5 µg proton pump inhibitor/ml.



Claim 304. (Withdrawn) The composition of claim 299, wherein within about 15 minutes after administration of a single dose of the composition to the subject, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 305. (Withdrawn) A method of treating a gastric acid related disorder in a subject in need thereof, comprising:

providing a solid pharmaceutical composition for oral administration to the subject, the composition comprising a therapeutically effective amount of at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid; and

orally administering the pharmaceutical composition to the subject;

wherein upon oral administration of a single dose of the composition to the subject, the composition provides a maximum serum concentration of the proton pump inhibitor of at least about 0.25 µg/ml, and within about 15 minutes after administration of the single dose, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

Claim 306. (Withdrawn) The method of claim 305, wherein the maximum serum concentration is at least about 0.5 µg/ml.

Claim 307. (Withdrawn) The method of claim 305, wherein the maximum serum concentration is at least about 0.75 µg/ml.

Claim 308. (Withdrawn) The method of claim 305, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.5 hours.



Claim 309. (Withdrawn) The method of claim 305, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 1 hour.

Claim 310. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor and an amount of at least one buffering agent sufficient to increase gastric fluid pH to a pH that prevents acid degradation of at least some of the proton pump inhibitor in the gastric fluid;

wherein the composition upon oral administration of a single dose to the subject, provides a maximum serum concentration of the proton pump inhibitor of at least about 0.25 µg/ml, and within about 15 minutes after administration of the single dose, a serum concentration of at least about 0.15 µg proton pump inhibitor/ml is obtained.

- Claim 311. (Withdrawn) The composition of claim 310, wherein the maximum serum concentration is at least about 0.5 µg/ml.
- Claim 312. (Withdrawn) The composition of claim 310, wherein the maximum serum concentration is at least about 0.75 µg/ml.
- Claim 313. (Withdrawn) The composition of claim 310, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 0.5 hours.
- Claim 314. (Withdrawn) The composition of claim 310, wherein the maximum serum concentration of the proton pump inhibitor is reached within about 1 hour.



Claim 315. (Withdrawn) A solid pharmaceutical composition suitable for oral administration to a subject, comprising: (a) at least one acid labile, substituted benzimidazole H<sup>+</sup>,K<sup>+</sup>-ATPase proton pump inhibitor in an amount of about 2 mg to about 300 mg; and (b) at least two buffering agents in a total amount sufficient to elevate pH of stomach secretions upon oral administration to the subject to prevent acid degradation of at least some of the proton pump inhibitor in the stomach secretions to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 30 minutes after ingestion of the composition; and

wherein if the composition is other than a dosage form selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, effervescent tablet, and troche, then the buffering agent is in an amount that is more than about 40 times the amount of proton pump inhibitor on a weight to weight basis in the composition.

Claim 316. (Withdrawn) The composition of claim 315, wherein the composition is a dosage form selected from the group consisting of tablet, capsule, powder, pellets, and granules.

Claim 317. (Withdrawn) The composition of claim 315, wherein the composition is a dosage form selected from the group consisting of suspension tablet, chewable tablet, effervescent powder, effervescent tablet, and troche.

Claim 318. (Withdrawn) The composition of claim 315, wherein the proton pump inhibitor is enteric coated prior to administration.

Claim 319. (Withdrawn) The composition of claim 315, wherein the proton pump inhibitor is selected from the group consisting of omeprazole, lansoprazole, rabeprazole, 13105589 02936354



esomeprazole, pantoprazole, pariprazole, and leminoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 320. (Withdrawn) The composition of claim 319, wherein the proton pump inhibitor is omeprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 321. (Withdrawn) The composition of claim 319, wherein the omeprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 322. (Withdrawn) The composition of claim 319, wherein the proton pump inhibitor is lansoprazole, or an enantiomer, isomer, tautomer, ester, amide, derivative, prodrug, free base, or salt thereof.

Claim 323. (Withdrawn) The composition of claim 322, the lansoprazole is present in the composition in an amount of about 2 mg, about 5 mg, about 10 mg, about 15 mg, about 20 mg, about 25 mg, about 30 mg, about 35 mg, about 40 mg, about 45 mg, about 50 mg, about 55 mg, about 60 mg, about 65 mg, about 70 mg, about 75 mg, about 80 mg, about 85 mg, about 90 mg, about 95 mg, about 100 mg, about 105 mg, about 110 mg, about 115 mg, or about 120 mg.

Claim 324. (Withdrawn) The composition of claim 315, further comprising at least one of an excipient, a pharmaceutically compatible carrier, a binder, a suspending agent, a 13105589 02936354





flavoring agent, a sweetening agent, a disintegrant, a flow aid, a lubricant, an adjuvant, a colorant, a diluent, a moistening agent, a preservative, a parietal cell activator, an anti-foaming agent, an antioxidant, a chelating agent, an antifungal agent, an antibacterial agent, or an isotonic agent, and combinations of any of the foregoing.

(Withdrawn) The composition of claim 315, wherein the buffering agent Claim 325. is selected from the group consisting of a bicarbonate salt of a Group IA metal, an alkali earth metal buffering agent, a calcium buffering agent, a magnesium buffering agent, an aluminum buffering agent, sodium bicarbonate, potassium bicarbonate, magnesium hydroxide, magnesium lactate, magnesium gluconate, magnesium oxide, magnesium aluminate, magnesium carbonate, magnesium silicate, magnesium citrate, aluminum hydroxide, aluminum phosphate, aluminum hydroxide/magnesium carbonate, potassium carbonate, potassium citrate, aluminum hydroxide/sodium bicarbonate coprecipitate, aluminum glycinate, aluminum magnesium hydroxide, sodium citrate, sodium tartrate, sodium acetate, sodium carbonate, sodium polyphosphate, sodium dihydrogen phosphate, potassium polyphosphate, sodium pyrophosphate, potassium pyrophosphate, disodium hydrogenphosphate, dipotassium hydrogenphosphate, trisodium phosphate, tripotassium phosphate, potassium metaphosphate, calcium acetate, calcium glycerophosphate, calcium chloride, calcium hydroxide, calcium lactate, calcium carbonate, calcium gluconate, calcium bicarbonate, calcium citrate, calcium phosphate magnesium phosphate, potassium phosphate, sodium phosphate, trihydroxymethylaminomethane, an amino acid, an acid salt of an amino acid, an alkali salt of an amino acid, and combinations of any of the foregoing.



- Claim 326. (Withdrawn) The composition of claim 315, wherein the total amount of the buffering agent is greater than about 10 mEq.
- Claim 327. (Withdrawn) The composition of claim 315, wherein the total amount of the buffering agent is greater than about 20 mEq.
- Claim 328. (Withdrawn) The composition of claim 315, wherein the total amount of the buffering agent present in the composition is about 16 mEq to about 150 mEq.
- Claim 329. (Withdrawn) The composition of claim 315, wherein the total amount of the buffering agent present in the composition is about 16 mEq to about 70 mEq.
- Claim 330. (Withdrawn) The composition of claim 315, wherein the total amount of the buffering agent present in the composition is about 16 mEq to about 55 mEq.
- Claim 331. (Withdrawn) The composition of claim 315, wherein at least one of the buffering agents is sodium bicarbonate.
- Claim 332. (Withdrawn) The composition of claim 331, wherein the amount of the sodium bicarbonate present in the composition is about 2 mEq to about 70 mEq.
- Claim 333. (Withdrawn) The composition of claim 331, wherein the amount of the sodium bicarbonate present in the composition is about 10 mEq to about 55 mEq.
- Claim 334. (Withdrawn) The composition of claim 331, wherein the amount of the sodium bicarbonate present in the composition is about 12.5 mEq to about 30 mEq.



Claim 335. (Withdrawn) The composition of claim 331, wherein the amount of the sodium bicarbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 336. (Withdrawn) The composition of claim 315, wherein at least one of the buffering agents is calcium carbonate.

Claim 337. (Withdrawn) The composition of claim 336, wherein the amount of the calcium carbonate present in the composition is about 2 mEq to about 70 mEq.

Claim 338. (Withdrawn) The composition of claim 336, wherein the amount of the calcium carbonate present in the composition is about 10 mEq to about 55 mEq.

Claim 339. (Withdrawn) The composition of claim 336, wherein the amount of the calcium carbonate present in the composition is about 12.5 mEq to about 30 mEq.

Claim 340. (Withdrawn) The composition of claim 336, wherein the amount of the calcium carbonate present in the composition is about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 341. (Withdrawn) The composition of claim 315, wherein the buffering agent is a mixture of sodium bicarbonate and calcium carbonate.

Claim 342. (Withdrawn) The composition of claim 341, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 16 mEq to about 70 mEq.



Claim 343. (Withdrawn) The composition of claim 341, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 16 mEq to about 50 mEq.

Claim 344. (Withdrawn) The composition of claim 341, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 16 mEq to about 30 mEq.

Claim 345. (Withdrawn) The composition of claim 341, wherein the amount of the sodium bicarbonate and calcium carbonate totals about 0.2 mEq, 1 mEq, 2 mEq, 3 mEq, 5 mEq, 10 mEq, 12.5 mEq, 15 mEq, 20 mEq, 25 mEq, 30 mEq, 50 mEq, 70 mEq, or 150 mEq.

Claim 346. (Withdrawn) The composition of claim 315, wherein all or part of the proton pump inhibitor is micronized.

Claim 347. (Withdrawn) The composition of claim 315, wherein all or part of the buffering agent is micronized.

Claim 348. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1 hour after administration of the composition.

Claim 349. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 15 minutes to about 1.5 hours after administration of the composition.



Claim 350. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.1 µg/rnl from about 15 minutes to about 1.5 hours after administration of the composition.

Claim 351. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml at any time within about 30 minutes after administration of the composition.

Claim 352. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to maintain a serum concentration of the proton pump inhibitor greater than about 0.15 µg/ml from about 10 minutes to about 30 minutes after administration of the composition.

Claim 353. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 20 minutes after administration of the composition.

Claim 354. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 15 minutes after administration of the composition.



Claim 355. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.15 \,\mu\text{g/ml}$  at any time within about 15 minutes after administration of the composition.

Claim 356. (Withdrawn) The composition of claim 315, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about  $0.10 \,\mu\text{g/ml}$  at any time within about 20 minutes after administration of the composition.

Claim 357. (Withdrawn) The method of claim 1, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 20 minutes after administration of the composition.

Claim 358. (Withdrawn) The method of claim 75, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 20 minutes after administration of the composition.

Claim 359. (Withdrawn) The method of claim 113, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 20 minutes after administration of the composition.



Claim 360. (Withdrawn) The composition of claim 154, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1  $\mu$ g/ml at any time within about 20 minutes after administration of the composition.

Claim 361. (Withdrawn) The composition of claim 192, wherein the composition is administered in an amount to achieve an initial serum concentration of the proton pump inhibitor greater than about 0.1 µg/ml at any time within about 20 minutes after administration of the composition.